

REMARKS/ARGUMENTS

Supplemental to the Amendment filed April 20, 2009 in response to the Rejection dated October 21, 2008, favorable reconsideration is respectfully requested in view of the Amendment submitted April 20, 2009, and the attached Declaration of Charli Kruse under 37 C.F.R. 1.132.

Favorable reconsideration is respectfully requested in view of the following remarks.

Rejection under 35 USC § 112 first paragraph

Claims 1-17 stand also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed for the reasons as set forth in the Amendment submitted April 20, 2009, and as further set forth below.

The Examiner argues that while the level of ordinary skill in this art is at the postdoctoral level, without a substantive teaching of the starting material, the method cannot be enabled. The Examiner further argues that even if the starting material were considered to be exocrine tissue (i.e., not necessarily stem cells), the specification in view of the art is insufficient to enable the claims across their entire scope.

The Examiner argues that the art of isolating pluripotent stem cells from exocrine tissue and trans-differentiating these cells to yield pancreatic hormone-producing cells (i.e., endocrine cells) must be considered "nascent," because a thorough search of the prior art found no such teachings at the time of the invention, so the amount of guidance required by applicant is relatively high. The Examiner further argues that only rat and human glandular tissue is employed in the working examples; there is no evidence that any tissue from an invertebrate could be used as the starting material for obtaining the pluripotent stem cells.

However, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Teletronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to

make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224 (CCPA 1971).

Here, the claims are enabled because there is not any reason to doubt the objective truth of the statements contained in the Specification for enabling support. The Specification discloses the manner and process for making and using the claimed invention, including working examples which show the efficacy of the claimed invention. As set forth in the Amendment submitted April 20, 2009, the Specification provides clear guidance for the skilled artisan which steps are necessary to obtain pluripotent adult stem cells from different exocrine glands and different species. The Examples specifically disclose the isolation of stem cells from two species, namely human and rat, and from two tissue sources, namely acinar tissue of the pancreas (Example 2) and exocrine tissues (acinar tissue and tubular tissue) of the parotid gland (Example 3). In addition, Example 10 shows the insulin production of the differentiated cells with a microscopic image (see Figure 8) of insulin-producing cells that were obtained from the exocrine pancreas of a human being, and that corresponding results have been found with salivary glands of a human being or of other vertebrates.

Thus, the Specification provides clear guidance for the skilled artisan which steps are necessary to obtain pluripotent adult stem cells from different exocrine glands and different species.

In addition, as noted by Dr. Kruse in his attached Rule 1.132 Declaration, a person reasonably skilled in the art would have been enabled by the original disclosure to produce isolated pluripotent adult stem (IPAS) cells from a variety of cell types from a variety of organisms without undue experimentation. The Declaration describes how experimental protocols described in the application were used to prepare IPAS cells from four different organs of fourteen different species of animals (see Declaration of Dr. Kruse at ¶7-8). This evidence is sufficient to establish that the full scope of the claims is enabled by the original disclosure.

Furthermore, the Declaration of Dr. Kruse under 37 CFR 1.132 presents experimental data. This experimental data includes evidence that pluripotent stem cells can be isolated from pancreatic tissue of another species, i.e. goat (see Declaration of Dr. Kruse at ¶9-12). The differentiated cells stained positive for several cell markers having specificity for different cells of all 3 germ layers. The differentiated cells stained positive for the ectodermal cell markers GFAP and neurofilaments (see Figure 1A and 1B). The differentiated cells stained positive for

the mesodermal markers collagen-II and α -smooth muscle actin (see Figure 2A and 2B). The differentiated cells stained positive for the endodermal marker cytokeratin 18 and amylase (see Declaration of Dr. Kruse at ¶11, and Appendix B, Figure 3A and 3B).

With respect to the confirmation of a normal karyotype, Dr. Kruse submits the results obtained by an independent cytogenetic laboratory located in Kaiserslautern, Germany. The findings of the independent cytogenetic laboratory are set forth in the summarizing opinion (see Declaration of Dr. Kruse, ¶12, and Appendix C, "Beurteilung") with respect to the specimen (translated from the German):

Numerically and structural inconspicuous female karyotype, the satellite extension at one chromosome 22 is a normal variation without pathologic relevance.

In addition, the Declaration of Dr. Kruse under 37 CFR 1.132 presents more experimental data regarding the characterization of IPAS cells isolated from salivary glands of African Boer Goats, (see Declaration of Dr. Kruse, ¶13-14). These cells stained positive for two stem cell markers (see Figure 4A and 4B) and the differentiated cells stained positive for several cell markers having specificity for different cells of all 3 germ layers: ectoderm (see Figure 5A, 5B and 5C), mesoderm (see Figure 6A and 6B) and endoderm (see Figure 7A and 7B).

With regard to the issue of whether the presence of nestin is indicative for a neuronal stem cell, Applicant has submitted the Kajahn reference (Kajahn, J., et al., Skin-derived human adult stem cells surprisingly share many features with human pancreatic stem cells. Eur. J. Cell Biol. (2007)) which demonstrates that the marker nestin as an indicator of pluripotency has been demonstrated for pancreatic stem cells and skin-derived cells (see Figs. 1 and 2 of Kajahn et al.).

Here, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into insulin producing cells. The Specification teaches that the pancreatic stem cells can differentiate into nerve cells, glial cells, muscle cells, cartilage, exocrine glandular cells, endocrine glandular cells and epidermal cells. Evidence has been submitted in the form of a 1.132 Declaration showing isolation of stem cells from goat, and well as other mammals, and that the cells maintain a normal karyotype. Thus, given the teachings of the Specification the quantity of experimentation required is not excessive in view of the subject matter of the claims. The Specification sets forth

methods for producing IPAS cells. Working Examples are also provided, as well as detailed information as to the methods. This information can be used by one of ordinary skill in the art to determine appropriate solution conditions to practice the claimed process, without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph is respectfully requested.

Rejection under 35 USC § 112 first paragraph

Claims 1-17 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed for the reasons as set forth in the Amendment submitted April 20, 2009, and as further set forth below.

The Examiner argues that a stem cell has two properties: it can produce differentiated progeny, and it can renew itself (citing Potten et al.). A pluripotent stem cell can differentiate into many different cell types (citing MedlinePlus). The Examiner argues that for a cell to be considered a "pluripotential stem cell," evidence must show that it can give rise to at least two different mature cell types and that it is self-renewing, and the Examiner argues that such evidence is lacking in this application. The Examiner argues that the specification in view of the art fails to provide sufficient teachings that the skilled artisan would conclude that applicants possessed a method including obtaining bona fide pluripotent stem cells from exocrine tissue; therefore, the specification cannot enable methods of making pancreatic hormone-producing cells from exocrine tissue pluripotent stem cells.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the

disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Here, as set forth in the Amendment submitted April 20, 2009, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into insulin producing cells. The Specification sets forth methods for producing IPAS cells. Working Examples are also provided, as well as detailed information as to the methods. Evidence has been submitted in the form of a 1.132 Declaration showing isolation of stem cells from goat, and well as other mammals, and that the IPAS cells maintain a normal karyotype.

Thus, given the teachings of the Specification the patent Specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Applicant clearly has established possession of the invention that is now claimed.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

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By 
Joseph F. Murphy
Registration No. 58,313
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

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